

July 12, 2005

MEMORANDUM TO: C. William Reamer, Director
Division of High-Level Waste Repository Safety
Office of Nuclear Material Safety
and Safeguards

FROM: Robert M. Latta, Senior Site Representative /RA/
Fuel Cycle & Decommissioning Branch
Division of Nuclear Material Safety
Region IV

Jack D. Parrott, Senior On-Site Licensing Representative /RA/
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Division of High-Level Waste Repository Safety
Office of Nuclear Material Safety
and Safeguards

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION ON-SITE LICENSING
REPRESENTATIVES' REPORT ON THE YUCCA MOUNTAIN
PROJECT FOR MARCH 1, 2005, THROUGH APRIL 30, 2005

The purpose of this memorandum is to transmit the U.S. Nuclear Regulatory Commission (NRC) On-Site Representatives' (ORs') report for the period of March 1, 2005, through April 30, 2005.

This report highlights a number of Yucca Mountain Project activities of potential interest to NRC staff. The ORs continue to respond to requests from NRC Headquarters staff to provide various documentation and feedback related to Key Technical Issues (KTIs) and their resolution. During this reporting period, the ORs continued to observe activities associated with Yucca Mountain site activities, KTIs, and audits. The ORs also attended various meetings and accompanied NRC staff on visits to Yucca Mountain.

In accordance with 10 CFR 2.390 of NRC's "Rules of General Applicability," a copy of this letter will be available electronically in NRC Public Document Room or from the Publicly Available Records component of the NRC's document system Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

If you have any questions on this report or its attachments, please call Robert Latta on (702) 794-5048, or Jack Parrott on (702) 794-5047.

Attachments:

1. "U.S. Nuclear Regulatory Commission On-Site Licensing Representatives' Report Number OR-05-02 for the Reporting Period of March 1, 2005, through April 30, 2005"
2. Table 1: "U.S. NRC On-Site Licensing Representatives' Tracking Report for Open Items Followed in Bi-Monthly OR Report"

cc: See attached list.

Memorandum to C. William Reamer, Director, from R. Latta and J. Parrott, dated: July 12, 2005
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C. Marden, BNL, Inc.
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G. Hernandez, Las Vegas Paiute Tribe
R. Arnold, Pahrump Paiute Tribe
G. Hudlow, Public Citizen
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B. Durham, Timbisha Shoshone Tribe
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C. Myers, Maopa Paiute Indian Tribe
R. Wilder, Fort Independence Indian Tribe
D. Vega, Bishop Paiute Indian Tribe
J. Egan, Egan, Fitzpatrick & Malsch
J. Leeds, Las Vegas Indian Center

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R. Joseph, Lone Pine Paiute-Shoshone Tribe
L. Tom, Paiute Indian Tribes of Utah
E. Smith, Chemehuevi Indian Tribe
D. Buckner, Ely Shoshone Tribe
D. Eddy, Jr., Colorado River Indian Tribes
V. Guzman, Inter-Tribal Council of NV
(Chairwoman, Walker River Paiute Tribe)
H. Jackson, Public Citizen
P. Thompson, Duckwater Shoshone Tribe
S. Devlin, Public Citizen
D. Irwin, Hunton & Williams
J. Donnell, MTS
R. Murray, MTS
B. Gattoni, Burns & Roe
J. Kennedy, Timbisha Shoshone Tribe
D. Crawford, Inter-Tribal Council of NV

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**U.S. NUCLEAR REGULATORY COMMISSION
ON-SITE LICENSING REPRESENTATIVES' REPORT
NUMBER OR-05-02,
FOR THE REPORTING PERIOD OF
MARCH 1, 2005, THROUGH APRIL 30, 2005**

TABLE OF CONTENTS

U.S. NUCLEAR REGULATORY COMMISSION
ON-SITE LICENSING REPRESENTATIVES' REPORT
NUMBER OR-05-02

FOR THE REPORTING PERIOD OF MARCH 1, 2005, THROUGH APRIL 30, 2005

PAGE

TABLE OF CONTENTS	i
ACRONYMS AND ABBREVIATIONS	ii
EXECUTIVE SUMMARY	1
REPORT DETAILS3
Introduction	
Objectives	
1. Site Activities and Data Acquisition	3
2. Outreach Activities	4
3. QA and Engineering	4
4. General Activities	10

ACRONYMS AND ABBREVIATIONS

ACRO	MEANING
ADAMS	Agencywide Documents Access and Management System
AMR	Analysis Model Report
BSC	Bechtel SAIC Company, LLC
CAP	Corrective Action Program
CR	Condition Report
DOE	U.S. Department of Energy
ECRB	Enhanced Characterization of the Repository Block
EPRT	Engineering Products Review Team
ESF	Exploratory Studies Facility
FY	Fiscal Year
KTI	Key Technical Issue
LA	License Application
MRC	Management Review Committee
NNPP	Naval Nuclear Propulsion Program
NRC	U.S. Nuclear Regulatory Commission
OQA	Office of Quality Assurance
OR	On-Site Representative
ORD	Office of Repository Development
PA	Performance Assessment
QA	Quality Assurance
QARD	Quality Assurance Requirements Description
RCA	Root-Cause Analysis
RIT	Regulatory Integration Team
SAR	Safety Analysis Report

EXECUTIVE SUMMARY

SITE ACTIVITIES AND DATA ACQUISITION

During this reporting period, the On-Site Representatives (ORs) were informed of seepage occurring in the Exploratory Studies Facility. An OR observed the seepage, the sampling of seepage water, and the Project's characterization of the seepage throughout the reporting period. The ORs' office received a letter from the Project, which contained a determination that the occurrence of this seepage was of "non-technical significance." By the end of the reporting period, the area of dripping had been reduced, but the Project's collection and analysis of the water samples and the event were continuing. See section 1 of "Report Details."

OUTREACH ACTIVITIES

On March 23, 2005, an OR attended the Project's Affected Units of Government meeting. See Section 2 of "Report Details."

EVALUATION OF CURRENT TREND INFORMATION

The Yucca Mountain Project's (YMP's) "Trend Evaluation Report" for the first-quarter fiscal year 05, was released on March 1, 2005. Based on the analysis of information contained in this report, three major contributors to the cause of Condition Reports (CRs) were identified. These contributors involved: 1) human performance errors, 57 percent; 2) management problems, 17 percent; and 3) communications issues, 11 percent (i.e., procedure content). The report also identified that analysis of the CRs classified as Level B generally indicated latent organizational weaknesses associated with change management that involves cross-departmental interfaces.

The ORs will continue to monitor the Project's human performance improvement initiatives, as well as requirements management processes. The results of these monitoring activities will be documented in a future report. See Section 3.1 of "Report Details."

OBSERVATION OF PROCUREMENT PROGRAM AUDIT

During this reporting period, the ORs observed selected aspects of the U.S. Department of Energy's (DOE's) Office of Quality Assurance compliance audit of Bechtel SAIC Company, LLC (BSC) procurement program. The audit team concluded that implementation of the procurement program was satisfactory and that the acquisition process was generally effective. However, the team identified a concern related to the number of conditions, adverse to quality, involving procedural non-compliance.

Based on the ORs' observations, it was determined that the audit team appropriately evaluated the effectiveness and implementation of the procurement program. No audit observations were identified and the ORs determined that this oversight activity was effectively performed. See Section 3.2 of "Report Details."

DEFICIENCIES RELATED TO DESIGN/ENGINEERING PRODUCTS

The ORs reviewed the current status of Level A, CR-3235, and the associated Root Cause Analysis (RCA). The original condition description for this CR identified potential deficiencies in the Project's Corrective Action Program process and included information related to ineffective corrective actions, inadequate extent of condition assessments, inappropriate reduction of initiator significance determinations on CRs, and the failure to recognize adverse trends.

Based on the ORs review of the documentation related to Level A CR-3235 and the associated RCA, several discrepant conditions were identified. Pending the resolution of these apparent discrepancies in the RCA for CR-3235, these issues are identified as **OR Open Item 05-01**. See Section 3.3 of "Report Details."

OBSERVATION OF BSC DESIGN CONTROL PROCESS AUDIT

From March 14 to 18, 2005, an OR observed the daily team meetings and management briefings of a limited-scope compliance audit of the BSC design control process conducted by BSC Quality Assurance (QA) in Las Vegas, NV. The conclusion of the audit was that BSC is satisfactorily and effectively implementing the Project's design control requirements. The OR determined that this oversight activity was appropriately performed and identified a noteworthy practice. See Section 3.4 of "Report Details."

OBSERVATION OF DOE's ANNUAL REVIEW OF THE NAVAL NUCLEAR PROPULSION PROGRAM QA ACTIVITIES

On April 27 and 28, 2005, an OR participated in NRC's observation of DOE's annual interface and exchange of information meeting with the Naval Nuclear Propulsion Program (NNPP). NRC representatives determined that DOE was meeting its requirements and procedure for assessing NNPP's QA activities. See Section 3.5 of "Report Details."

REVIEW OF OPEN ITEMS

The ORs reviewed the pertinent information associated with OR Open Item 03-03. This item concerned inadequacies, in the planning documents associated with Analysis Model Reports, which did not provide the necessary information to demonstrate compliance with the established validation criteria.

Based on the review of the completed corrective and preventive actions related to this issue, the ORs determined that the identified concerns had been effectively resolved. Therefore, **OR Open Item 03-03** is considered closed. See section 3.6 of "Report Details."

GENERAL ACTIVITIES

An OR visited the site on March 7 and 21, 2005, to observe active or potential seepage areas. See Section 1 of "Report Details."

REPORT DETAILS

INTRODUCTION

The principal purpose of the On-Site Representatives' (ORs') report is to inform U.S. Nuclear Regulatory Commission (NRC) managers, staff, and contractors about information on the U.S. Department of Energy's (DOE's) programs in repository design; performance assessment (PA); performance confirmation; and environmental studies that may be useful in fulfilling NRC's role during prelicensing consultation. The primary focus of this and future OR reports will be on DOE's programs for subsurface and surface-based testing, PA, data management systems, environmental studies, and quality assurance (QA). Relevant information includes new technical data, DOE's plans and schedules, and the status of activities to support preparation of the License Application (LA). The ORs also take part in activities associated with resolving NRC Key Technical Issues (KTIs). This report covers the period of March 1, 2005, through April 30, 2005.

OBJECTIVES

An OR's mission is to serve principally as a point of prompt information exchange and to identify preliminary concerns with site investigations and potential licensing issues. The ORs carry out this role by gathering and evaluating information, identifying concerns, and bringing more significant issues to NRC management's attention. Communication with DOE is accomplished by exchanging information on data, plans, schedules, documents, activities and pending actions, and resolution of issues. The ORs interact with DOE scientists, engineers, and managers, with input from NRC Headquarter's management, regarding the implementation of NRC policies, programs, and regulations. The ORs also focus on such issues as design controls, data management systems, PA, and KTI resolution. A primary OR role is to identify areas in site studies, activities, or procedures that may be of interest or concern to the NRC staff.

1. SITE ACTIVITIES AND DATA ACQUISITION

1.1 Seepage Observation in the Exploratory Studies Facility (ESF)

On March 1, 2005, the ORs were informed by DOE that seepage, apparently from infiltration of rain, was observed in the south ramp of the Yucca Mountain Exploratory Studies Facility (ESF) on February 28, 2005. The seepage was occurring along a 40-meter section of the ESF, located approximately 270 to 310 meters from the south portal. The nature of the seepage was water running down the sides of the ESF, as well as dripping from fracture areas and rock bolts in the crown of the tunnel at discrete locations along the 40-meter section. This section of the ESF lies under approximately 40 meters of overburden consisting of fractured tuff from the Tiva Canyon Formation. The seepage was pronounced enough to be observed despite the drying effect of ventilation in the ESF.

On March 7, 2005, the OR entered the south ramp and observed the seepage area and the Project's collection of samples of the water dripping from the crown of the ESF. There were multiple points along the 40-meter section that were actively dripping. On March 21, 2005, an OR participated in a Project entry of the Enhanced Characterization of the Repository Block (ECRB). This was done in part to see if seepage was occurring along the Solitario Canyon fault at the point where the ECRB penetrates it. On the date of the entry, no seepage was observed, and it did not appear that any had occurred.

On March 23, 2005, the ORs' office received a letter from the Project, which forwarded a "Report of Unexpected Geologic Condition," with a determination that the occurrence of this seepage was of "non-technical significance." The Project monitored the seepage, collected water samples for analysis, and further characterized the seepage throughout the reporting period. As of the end of the reporting period, the area of dripping had been reduced down to two discrete points and the Project's analysis of the water samples and the event were continuing. The ORs will continue to monitor DOE's response to this event and the results of any analysis.

2. OUTREACH ACTIVITIES

2.1 DOE Affected Units of Government Meeting

On March 23, 2005, an OR attended the Project's Affected Units of Government meeting. Updates from DOE included those on the overall Project and the national transportation program. There were also discussions on the U.S. Geological Survey potential records' falsification issue and the potential for that issue to impact the submittal of an LA.

3. QA AND ENGINEERING

3.1 Evaluation of Current Trend Information

The Yucca Mountain Project's "Trend Evaluation Report" for the first-quarter fiscal year (FY) 2005, was released on March 1, 2005. This report is an integral part of the Corrective Action Program (CAP) and is used to identify patterns and the causes of Condition Reports (CRs), so that management can identify effective resolutions. The report used the source data from adverse conditions associated with Office of Repository Development activities, from the previous 12 months, January 1 to December 31, 2004. (The adverse conditions include those CRs classified as Level A, B, or C).

Based on the analysis of information contained in this report, three major contributors to the causes of CRs were identified. These contributors involved: 1) human performance errors, 57 percent; 2) management problems, 17 percent; and 3) communications issues, 11 percent (i.e., procedure content). These values represent approximately the same relative distribution as reported in the previous trend report. As stated in the report, "The distribution and relative significance classification among the human-performance-management- and procedure-content-related causal factors are consistent with the project's human performance model." However, the report also identified that analysis of the CRs classified as Level B generally indicates latent organizational weaknesses, associated with change management, that involves cross-departmental interfaces. Specifically, these problems involved not having all requirements properly reflected in implementing procedures and process activities that were not consistently performed. Examples include procedures AP-16.1Q, "Condition Reporting and Resolution," and LP-BSC-1.0Q, "Organization," not meeting all the quality requirements -- and AP-3.12Q, "Design Calculations and Analysis," not being adequate to control design calculations.

As noted in the report, these procedures had been through the review and approval process, were in use, and were subsequently determined to have deficiencies that required procedural revisions. The adverse conditions related to these procedures were documented on CR 4787, for further evaluation of cross-departmental process related to

procedural incorporation of requirements.

The trend report also identified that the number of reported adverse conditions had increased from approximately 50 per month, to approximately 100 per month, for the first quarter of FY 05. This increase was attributed to the extent-of-condition review associated with CR-3235, and reviews related to procedures and requirements management activities.

The ORs will continue to monitor the Project's human performance improvement initiatives, as well as requirements management processes, and the results will be documented in a future report.

3.2 Observation of Procurement Program Audit

During this reporting period, the ORs observed selected aspects of DOE's Office of Quality Assurance compliance audit of BSC's procurement program. Specifically, the audit team evaluated the effectiveness of BSC's procurement process and the adequacy of implementing documents to ensure compliance with the requirements of the Quality Assurance Requirements and Description (QARD). The audit scope also included the review of previously identified CRs, to establish the effectiveness of completed corrective actions, and to determine if recurring deficiencies were identified.

Procurement-related activities evaluated by the audit team included training of procurement personnel, management or organizational self-assessments, supplier evaluation/audits, procurement documents, and QA records. Within these areas, the audit team examined interfacing organizations such as: Records Management, Design/Engineering, and Licensing involved in the procurement process -- as well as BSC's QA evaluations and audits of suppliers. As a result of these evaluations, the audit team identified four Level B CRs and eight Level C CRs. Two of the Level B CRs documented: (1) a quality-affecting procedure that did not appropriately address specific QARD requirements concerning Training and Procurement Document Control; and (2) a failure to properly include a change history in a controlled document. The third Level B CR identified ineffective remedial and corrective actions concerning the evaluation of a supplier deviation report. The fourth Level B CR noted a potential adverse trend involving ineffective remedial and corrective actions. The audit team also determined that the corrective actions for six of the 11 previously issued CRs were ineffective.

The audit team concluded that implementation of the procurement program was satisfactory and that the acquisition process was generally effective. However, the team identified a concern related to the number of conditions adverse to quality involving procedural non-compliance, which may indicate the need for increased management attention.

Based on the ORs' observations, it was determined that the audit team appropriately evaluated the effectiveness and implementation of the procurement program. No audit observations were identified and the ORs determined that this oversight activity was effectively performed.

3.3 Deficiencies Related to Design/Engineering Products

The ORs reviewed the current status of Level A, CR-3235, issued on July 22, 2004. The original condition description for this CR identified potential deficiencies in the

Project's CAP process and included information related to ineffective corrective actions, inadequate extent of condition assessments, inappropriate reduction of initiator-significance determinations on CRs, and the failure to recognize adverse trends. The CR also noted a number of previously documented instances involving poor development and checking of technical products. In conjunction with these reviews, the ORs examined the "Root-Cause Analysis," (RCA) report for CR 3235, dated February 2005.

3.3.1 Background:

Subsequent to the identification of this issue, the Project's Management Review Committee (MRC) determined that CR-3235 identified several separate, but related, problems. To focus on the evaluation of these problems, the MRC subdivided three of the issues identified in CR-3235 and documented them on separate CRs (3347, 3348, & 3349). The respective problem statements for these CRs, which are referenced back to CR 3235, involve the following issues:

- The adverse trends, related to errors in issued documents identified in CR 2263, were not fully evaluated for the underlying causes and extent of condition.
- The project trend program did not appropriately identify an adverse trend documented in CR-3235.
- CR significance determinations are downgraded for the sake of expediency, trending is not effective, and feedback to the CR originator is inadequate.

The problem statement for CR-3235 was revised from issues related to the CAP, to focus corrective and preventive actions on deficiencies related to traceability, transparency, and technical errors in design documents supporting the Safety Analysis Report (SAR). To address the revised problem statement for CR-3235, BSC chartered two teams, the Engineering Products Review Team (EPRT) and the RCA team.

In late August 2004, an RCA Charter was developed and an initial RCA was initiated, to evaluate the revised condition description for CR-3235. The RCA team completed its evaluation and provided a draft final version of its report, to DOE, for review in late September 2004. The draft report identified two primary root causes involving: 1) less than adequate organizational understanding of what constitutes a quality product; and 2) continuous design changes and increased technical work scope resulting in insufficient time to complete the work satisfactorily. In response to the draft root-cause report, DOE identified concerns with the content and completeness of the RCA, which did not identify the extent of condition nor the causal factors accurately enough to develop the requisite corrective and preventive actions.

In mid-October, 2004, BSC revised the RCA team charter and the effort to complete the supporting analysis was resumed. The revised charter expanded the focus of the RCA team and modified the team's composition. Based on the revised condition description for CR-3235, the RCA team developed "Problem Statements" to determine the causal factors that resulted in issues regarding the traceability, transparency, technical quality, and technical content of the documents supporting the SAR. The extent of condition determination for these problem statements was conducted in two parts. The EPRT assessed the extent of condition for the traceability, transparency, and technical quality issues and the RCA team evaluated the extent of condition for the technical consistency issue.

3.3.2 RCA Findings

Based on the results of the above noted reviews, the RCA team determined that there were a number of instances in which the traceability, transparency, and/or consistency of technical content of documents supporting the SAR did not meet the Project's standards and/or management expectations. The team also established that if not corrected, this condition could lead to additional effort to understand certain aspects of the technical basis that supports the design of the repository. The RCA Report also states, in part, that "...during the traceability, transparency, and technical quality extent of condition determination, the EPRT found no instances where the design product was not technically supportable. Thus the technical quality component of problem statement was not part of the analysis" However, based on the evaluation of the Type 4 CRs generated as a result of the EPRT review and examination of the associated EPRT report, the ORs identified a potential discrepancy in the RCA report. Specifically, the ORs determined that several of the CRs initiated in response to the EPRT review documented technical quality errors in engineering documents as they related to quantitative or qualitative acceptance criteria. Therefore, the population of Type 4 errors identified by the EPRT appears to include examples where critical attributes did not meet requirements, such as calculation errors, and cases where transparency and traceability did not meet project expectations. Based on these reviews, the rationale for exclusion of the technical quality aspect of the analysis from the RCA does not appear to be supported by the empirical data.

The ORs also noted apparent inconsistencies in the root-cause statements developed by the RCA team. Specifically, the root cause related to the traceability and transparency issues concluded that: "The guidance provided to those who develop technical products is not sufficient to ensure that management's stated expectations for product traceability and transparency are achieved." As stated in the RCA report, "The term **guidance** [emphasis added] as used in this instance refers to the suite of processes, implementing documents (**procedures**, [emphasis added] plans, etc.), and other written documents (guides, interoffice memos, e-mails, etc.) used to direct the production of technical products, as well as the guidance provided through interactions between management/supervision and those who develop technical products." Additionally, the RCA team documented numerous examples of inadequate procedural controls, related to design input information, in Appendix L of its report. However, the characterization of the term "guidance" was subsequently changed in CR-3235 to exclude reference to quality-affecting procedures. Therefore, the associated corrective actions for CR-3235 do not address revisions to procedures that were identified in the RCA as less than adequate.

The ORs identified a further concern related to the need to evaluate the conditions identified by the EPRT in CR-4159 for a stop-work condition. The ORs' reviews within this area indicated that because CR-4159 was classified as a Level B CR, a stop-work evaluation was not performed. As described in the controlling procedure for stop-work orders, a stop-work condition exists when continuing work would cause a significant breakdown or failure, in the implementation of QA Program requirements that compromises the quality of items or activities important to safety or waste isolation. Although a stop-work evaluation was performed for CR-3235 by the initial RCA, the documentation of the extent of condition in the initial RCA was determined by DOE to be incomplete and the basis for the identified conditions adverse to quality were indeterminate. Based on the ORs reviews within this area, it was determined that as a

result of the findings of the EPRT and the extent of condition related to the Type 4 errors documented in CR-4159, the basis for the Level A CR determination, and therefore the need for a stop-work evaluation associated with CR 3235, was effectively reestablished.

The ORs also noted as a result of CR-4159, the condition description for CR-3235 and the RCA team charter were revised to shift the focus of the evaluation from the CAP process to deficiencies concerning traceability, transparency and technical errors in design documents. Therefore, a re-evaluation of the relevant conditions associated with the adequacy of the design control process, in accordance with procedural requirements, should have been performed, based on the results of CR-4159.

3.3.3 Conclusion:

Based on the ORs review of the documentation related to Level A, CR-3235 and the associated RCA, several discrepant conditions were identified. Specifically, the ORs determined that the basis for exclusion of the technical quality aspect of the analysis (i.e., calculation errors) from the scope of RCA does not appear to be supported by existing data. The ORs also noted an apparent inconsistency in the characterization of the term “guidance” in the root cause statement, which initially addressed procedures but was subsequently changed to exclude reference to program requirements contained in procedures. As a result of this change in the scope of the root cause statement, the corrective actions for CR-3235 do not appropriately address revisions to procedures that were identified as less than adequate during the root-cause evaluation. The ORs identified a further concern related to the need to evaluate the conditions identified in CR-4159 for a stop-work condition. Therefore, pending the resolution of these apparent discrepancies in the RCA for CR-3235, these issues are identified in **OR Open Item 05-01**.

3.4 Observation of BSC Design Control Processes Audit

From March 14 to 18, 2005, an OR observed the daily team meetings and management briefings of a limited-scope compliance audit of the BSC design control process conducted by BSC QA in Las Vegas, NV. The focus of the audit was on the design products related to the Fuel-Handling Facility. The conclusion of the audit was that BSC is satisfactorily and effectively implementing Section 3.0, “Design Control,” of the Project’s QARD, Rev. 16, and its implementing procedures.

Based on the OR’s observations, it was determined that the audit team was well prepared and effectively examined the documentation. No audit observation inquiries were identified, and the OR determined that this oversight activity was appropriately performed. In addition, it is worth noting that although this was a compliance-based audit, the audit team identified a performance-based condition related to the inconsistent approach, to fire protection in moderator control areas, between three different design documents used for the Fuel-Handling Facility. These inconsistencies derived from changes in the approach to fire protection in moderator control areas, during 2004, when Project management made a decision that water sprinkler fire suppression should be provided to those areas. The design personnel knew of the inconsistencies, but no tracking mechanism had been provided to ensure that these issues were rectified across the relevant design documents. The OR considered the identification of a performance-based condition, during a compliance-based audit, a noteworthy practice.

3.5 Observation of DOE's Annual Review of the Naval Nuclear Propulsion Program QA Activities

On April 27 and 28, 2005, an OR participated in NRC's observation of DOE's annual interface and exchange of information meeting with the Naval Nuclear Propulsion Program (NNPP). This meeting was held to evaluate the implementation of, and revisions to, the NNPP QA program associated with NNPP's input to the Yucca Mountain repository LA over the last year. DOE made the preliminary conclusion, subject to review of documents, that the NNPP QA program controls were being effectively implemented and that they met 10 CFR 63.142 requirements. NRC representatives determined that DOE was meeting its requirements and procedure for assessing NNPP's QA activities.

3.6 Review of Open Items

During this reporting period, the ORs reviewed the pertinent information associated with a previously identified OR Open Item. The following is the result of the review.

As previously documented in NRC Report OR 03-02, dated June 11, 2003, the ORs evaluated DOE's progress in implementing corrective actions for CR 99 (previously CAR BSC-01-C-001), concerning model validation. As a result of these reviews, it was determined that the planning documents associated with Analysis Model Reports (AMR) did not provide the necessary information to demonstrate compliance with the validation criteria. Specifically, less than 20 percent of the documents reviewed provided adequate model validation criteria to evaluate whether these criteria were met in the AMR.

Subsequent to the identification of Open Item 03-03, similar deficiencies related to model validation were identified during the performance of QA oversight activities and during the conduct of OQA's verification activities related to CR 99. As a result of these repetitive conditions and concerns related to traceability and transparency issues, BSC initiated comprehensive corrective actions to address the completeness and accuracy of technical information in all of the AMRs. These actions included the detailed review of all of the AMRs in accordance with the work plan established for BSC's Regulatory Integration Team (RIT) process.

Prior to the closure of CR 99, OQA performed a final verification of all 51 of the model reports revised through the RIT. As a result of this verification effort, eight of the reports were found to have model-validation related deficiencies. The deficiencies related to three of these model reports were corrected and verified prior to the closure of CR 99. CR 4961 was issued to track the five remaining model reports through its revision cycle, which is currently scheduled for June 2005.

Based on the review of the closure information related to CR 99 and the completion of the associated corrective and preventive actions described above, the ORs determined that the issues identified in OR Open Item 03-03 have been resolved effectively. Therefore, **OR Open Item 03-03** is closed.

4. **GENERAL ACTIVITIES**

4.1 Yucca Mountain Site Visits

An OR visited the site on March 7, and 21, 2005, to observe active or potential seepage areas.

**U.S. NRC ON-SITE LICENSING REPRESENTATIVES' TRACKING REPORT FOR OPEN ITEMS FOR
BI-MONTHLY OR REPORT**

<i>OPEN ITEM NUMBER (For Tracking only)</i>	<i>BRIEF DESCRIPTION OF OPEN ITEM</i>	<i>OPEN ITEM OR REPORT NO.</i>	<i>DATE</i>
AOI-YMSCO-ARC-02-12-01	Identifies the need for DOE OQA to ensure that procedure development and review process include a documented evaluation to verify compliance with the requirements of the YMP's QARD.	OR-03-01	
OR Open Item 05-01	Inconsistencies in the root cause statements developed by the RCA team specifically the root cause related to traceability and transparency issues. Pending resolution of the apparent discrepancies in the RCA for CR-3235 are identified in this Open Item.	OR-05-02	
OR Open Item 04-01	A concern regarding the safety analysis of the ground support system in the ESF.	OR-04-01	
OR Open Item 03-06	Based on review of CR-756, 12 quality-affecting procedures were approved without meeting the applicable QARD requirements.	OR-03-05	
OR Open Item 03-05	The continued use of unqualified software in quality-affecting technical products appears to be in conflict with the governing requirements of the implementing procedures and the QARD.	OR-03-04	
OR Open Item 03-04	With a tentative date of mid-June to evaluate CAR BSC(B)-03-©)-107, the RCD has not acted on this CAR in a timely manner and it has remained open for 4 months without resolution.	OR-03-03	
OR Open Item 03-03	An evaluation in DOE's progress in implementing corrective actions associated with CAR B.C.-01-C-001, concerning model validation, the OR reviewed TAPS (approx. 43 models). Based on the results, it could not be established if the evaluation criteria will result in the development of models with adequate confidence for the LA.	OR-03-02	
OR Open Item 03-02	During a review of the MII confirmation packages, it was identified that the action statement execution task descriptions and completion schedules for many of the reviewed pkgs had been modified without appropriate justification. Therefore, pending the resolution of this apparent deviation from a commitment to administer the MII in accordance with the requirements of AP-5.1Q, this issue is identified as this OR Open Item.	OR-03-02	

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BI-MONTHLY OR REPORT**

<i>OPEN ITEM NUMBER (For Tracking only)</i>	<i>BRIEF DESCRIPTION OF OPEN ITEM</i>	<i>OPEN ITEM OR REPORT NO.</i>	<i>DATE</i>
OR Open Item 03-01	This Open Item is based on issues on separate DRs: (1) the effective resolution of concerns related to inadequate personnel training; 2) the failure to establish an effective transition plan; and 3) the evaluation of the SCWE issues.	OR-03-01	
OR Open Item 02-13	The current status of corrective & preventive actions associated with CAR No. BSC-02-C-01 revealed that not all corrective actions stated had been complete.	OR-02-05	
OR Open Item 02-12	Contrary to requirements of the QARD Supplement III 2.4.C, AP-SIII.2Q inappropriately allows for the use of unqualified data. BSC QA procedure change control program failed to identify this issue.	OR-02-05	
OR Open Item 02-11	Based on surveillance not identifying specific problems with software functionality for codes tested, 7 - including NUFT, did not pass ITP and/or VTP surveillance.	OR-02-05	
OR Open Item 02-10	Pending appropriate evaluation and documentation of the design control attributes associated with requirements of 10 CFR 63.44 and 10 CFR Part 21.	OR -02-04	
OR Open Item 02-09	Pending revision of engineering procedures, to include appropriate design verification considerations.	OR-02-04	
OR Open Item 02-08	The required performance of annual audits' justification for delaying a scheduled audit of YMSCO for 3 months, with an additional extension, does not appear to be adequately supported. Deviation from requirement of sub-section 18.2.1E of the QARD.	OR-02-04	
OR Open Item 02-07	Model Validation Impact Assessment addressed the effect of inappropriately validated models on TSPA-SR. Many cases of impact assessments used TSPA-SR results to evaluate the local impacts. It's unclear how this practice evaluated the cumulative impact of all the models in question.	OR-02-01	
OR Open Item 02-06	Unqualified Data Impact Assessment - NRC staff identified unqualified data that could be replaced with qualified data for the performance assessment. For the risk-significant components, an evaluation of unqualified data replaced with qualified data would help determine if efforts should be undertaken to qualify the removed data.	OR-02-01	

**U.S. NRC ON-SITE LICENSING REPRESENTATIVES' TRACKING REPORT FOR OPEN ITEMS FOR
BI-MONTHLY OR REPORT**

<i>OPEN ITEM NUMBER (For Tracking only)</i>	<i>BRIEF DESCRIPTION OF OPEN ITEM</i>	<i>OPEN ITEM OR REPORT NO.</i>	<i>L</i>
OR Open Item 02-05	Provisions are in place that allow for model validation to continue past issuance of the documentation. The models used in the performance assessment should have adequate support for their representation at the time the performance assessment documentation is issued.	OR -02-01	
OR Open Item 02-04	A number of criteria have been developed related to various forms of review. If a review is relied on for model validation, it should be directed at validating the model and it should encompass the full body of information to the extent practical.	OR-02-01	
OR Open Item 02-03	More objective criteria (comparison to data not used in the development of the model), typically resulting in higher confidence in model validation are not distinguished from the more subjective, problematic criteria.	OR-02-01	
OR Open Item 02-02	Current process controls specify that one or more of nine criteria may be used to validate a model. All the criteria should increase confidence in the modeling process, some criteria do not appear to be appropriate for addressing whether the model is valid for its intended use.	OR-02-01	
OR Open Item 02-01	Failure to properly include the specific issues identified in the Concerns Program Final Report in the resolution process may result in not adequately addressing the original employee's concern.	OR-02-01	